

Application No. 10/810,089
Amendment dated NOVEMBER 22, 2005
Reply to Final Office Action dated September 23, 2005

REMARKS

Applicants have carefully reviewed the Office Action dated September 23, 2005. In the Office Action, claims 1-5, 7, 8, 12, 13, 15, 17, 18 and 20-23 were rejected and claims 6, 9-11, 14, 16, 19 and 24-40 were withdrawn.

Claim Rejections—35 U.S.C. § 102

Claims 1, 2, 4, 5, 7, 8, 12, 13, 15, 22 and 23 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Hegde et al. (U.S. Patent No. 6,231,543). Applicants respectfully traverse the rejection because Hegde et al. do not disclose each and every element of the claimed invention.

For example, claim 1 recites a “radiopaque coating comprising a radiopaque material disposed within a non-metallic coating material that is applied to the surface of the segment of the shaft in a fluid state and cured.”

In the Office Action on page 3, the Examiner noted that this is a product-by-process element and consequently the step of making has not been given patentable weight. Applicants respectfully disagree that claim 1 is a product-by-process claim and assert that the language in the claim is structural in nature and, consequently, be given appropriate patentable weight.

A product-by-process claim is one in which the product is defined at least in part in terms of the method or process by which it is made. Bonito Boats Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141 (1989) citing D. Chisum, Patents §8.05, pp. 8-67 (1988). Therefore, in determining whether claim 1 is a product-by-process claim, the analysis becomes focused on particular claim limitations and on whether or not those limitations are process or structural in nature.

Process-sounding words such as “welded, intermixed, ground in place, press fitted, and etched” should be considered structural “when the process limitation imparts distinctive structural characteristics to the final product.” In re Garnero, 412 F.2d 276 (C.C.P.A. 1969). Like the “process limitations” cited in Garnero, the limitation in claim 1 imparts a distinctive structural characteristic of the final product claimed. Following the holding of Garnero, the language in claim 1 should be considered structural in nature.

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Numerous other cases as well other persuasive authority also point out that some limitations that appear to be process limitations are actually structural in nature. One commentator used a straightforward example to illustrate this point:

For example, the word 'frozen,' though descriptive of the freezing process, definitely describes an objective characteristic observable by inspection of the product. The courts have held a variety of such words not to be process limitations; typical are: 'intermixed' as descriptive of a composition of matter, 'ground in place' as descriptive of the manner in which spark plug porcelain is fitted into its shell, and 'pressfitted' as descriptive of a sheet metal structure. Saxe & Levitt, "Product-by-Process Claims and Their Current Status in Chemical Patent Office Practice," 42 J. Pat. Off. Soc'y 528, 536 (1960).

Similarly, in the Hazani case, the patentee wished to have the phrase "chemically engraved" considered a product-by-process limitation. Hazani v. U.S. Int'l Trade Comm'n, 126 F.3d 1473 (Fed. Cir. 1997). The Federal Circuit refused to do so and, instead, held that language in question was structural in nature because when "read in context, [the limitation] describes the product more by its structure than by the process used to obtain it." *Id.* at 1479. Similarly, in the R2 Medical Systems case, an Illinois District Court indicated that the word "affixed" means "to be attached physically" and that recitation of the word "affixed" does not refer to the process of affixing but rather the structural result. R2 Medical Systems, Inc. v. Katecho, Inc., 931 F.Supp. 1397, 1425-26 (N.D. Ill. 1996).

Applicants further note that the terms of claim 1, "disposed," "applied" and "cured" are all past participles used in an adjectival and not a verbal sense. In other words, claim 1 is not attempting to claim the processes of disposing, applying or curing, but rather it is attempting to claim the structural result. Applicants would also note that in the Office Action of April 14, 2005, claim 24 was withdrawn by the examiner because it was a product-by-process claim. Such an objection was not raised with any of the other claims, indicating that at that time, those other claims were not interpreted as product-by-process claims.

With the above remarks in mind, Applicants respectfully submit that the language of claim 1 should be considered to define a structural aspect of the claimed invention and be given the appropriate patentable weight. Therefore, in order to anticipate claim 1, a reference must disclose or teach the same structure.

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The structure imparted by the "radiopaque coating comprising a radiopaque material disposed within a non-metallic coating material that is applied to the surface of the segment of the shaft in a fluid state and cured" of claim 1 includes, for example, the following. The inner surface of the radiopaque coating is in contact with the surface of the portion of the shaft on which it is disposed. This contact is immediate (e.g. not separated by adhesives, fluxes, gaps created by variations in manufacturing tolerances, or the like) and extends over the entirety of the surface of the portion of the elongate shaft on which it is disposed. Further, there is a bond between the surface of the shaft and the inner surface of the radiopaque coating along the entire area of contact.

Hegde et al. disclose a dilation catheter having a catheter shaft with an inner guidewire lumen and an inflatable balloon. However, Hedge et al. do not disclose a radiopaque coating as claimed in claim 1, namely "a radiopaque coating disposed on a surface of a portion of the elongated shaft, the radiopaque coating comprising a radiopaque material disposed within a non-metallic coating material that is applied to the surface of the segment of the shaft in a fluid state and cured."

Hegde et al. disclose an embodiment that includes a sleeve 50 that is secured to shaft 10. "The sleeve is of a rigid or semi-rigid material" and "is secured to shaft 10 at locations proximal and distal to the valve." Column 5, lines 1-3. Moreover, "the sleeve is perforated or otherwise porous to allow for fluid communication between the interior of balloon 20 and valve 40." Column 5, lines 5-7. Neither this embodiment, nor any other disclosed by Hegde et al. anticipates claim 1. As discussed above, a coating that is applied to the surface of the segment in a fluid state and cured, such as that of claim 1, has the structural difference of adhering to the surface of the segment along the length of the coating and is not secured only at proximal and distal locations. To illustrate the difference from another angle, if the coating of claim 1 were applied to shaft 10 of Hegde et al., the coating would adhere both to shaft 10 and valve 40 and would render the valve inoperative. It is therefore easy to see that the sleeve 50 of Hegde et al. does not correspond to the coating of claim 1.

One particular embodiment of sleeve 50 merits further discussion. Hegde et al. disclose that "for metal sleeves, a radiopaque material can be coated onto the sleeve." Column 5, lines 19-20. This embodiment is inapposite for at least two reasons. First, claim 1 recites "the

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radiopaque coating comprising a radiopaque material disposed within a non-metallic coating material." Hegde et al. do not disclose what the radiopaque material that can be coated onto the sleeve might be, and do not teach or suggest that the radiopaque coating comprises a radiopaque material disposed within a non-metallic coating material. Second, claim 1 recites that the "radiopaque coating disposed on a surface of a portion of the elongated shaft" and "an expandable member affixed to the distal portion of the elongated shaft." In Hegde et al., the radiopaque coating is not disposed on shaft 10 that has an expandable member affixed to a distal portion thereof, but rather is disposed on sleeve 50. No expandable member is affixed to a distal portion of sleeve 50. Therefore, the radiopaque material of this embodiment does not correspond to the coating of claim 1.

As Hegde et al. do not disclose each and every element of claim 1, Applicants submit that claim 1 is in condition for allowance. As claims 2, 4-5, 7-8, 12-13, and 15 depend from claim 1 and contain additional elements, Applicants submit that these claims are in condition for allowance as well.

Claim 22 recites "coating means for rendering a portion...identifiable under fluoroscopy, wherein the coating means is applied in a fluid state and cured." As discussed above with regard to claim 1, Hegde et al. do not disclose such a coating means. Applicants therefore submit that this claim is allowable over Hegde et al.

Claim 23 recites "the radiopaque portion applied to the surface of the segment of the shaft in a fluid state and cured." For the reasons given above with respect to claim 1, Applicants submit that this claim is allowable over Hegde et al.

Claims 1, 2, 4, 5, 7, 8, 12, 13, 15, 17, 18, 21 and 22 were rejected under 35 U.S.C. § 102(e) as being anticipated by Voyles et al. (U.S. Patent No. 6,540,721). Applicants respectfully traverse the rejection.

Voyles et al. disclose a balloon catheter having an inner tubular member and an outer tubular member. The balloon catheter has a radiopaque marker 24 that is formed either "by doping a portion of the distal inner tubular member" or from "a separate discrete member which is preformed and subsequently secured to the distal section of the distal inner tubular member 20." Column 3, lines 34-35 and 41-44. Nowhere do Voyles et al. disclose a

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"radiopaque coating comprising a radiopaque material disposed within a non-metallic coating material that is applied to the surface of the segment...in a fluid state and cured", as claimed in independent claims 1 and 17. As discussed above, the bond between the radiopaque coating and the surface of the segment inherently extends along the length of the surface of the portion of the elongated shaft due to the nature of the bonding process. This is not the case for a bond that is preformed and subsequently secured. None of the methods of bonding mentioned in Voyles et al., "an adhesive bond, a solvent bond, heat fusing of the radiopaque marker" require the bond to extend along the length of the surface of the portion of the shaft. Column 3, lines 51-52. As MPEP 2112 says "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Because the structure of the inventions of claim 1 or 17 is not disclosed explicitly or inherently by Voyles et al, applicants submit that these claims are in condition for allowance. As claims 2, 4, 5, 7, 8, 12, 13, 15 and 18 depend from either claim 1 or claim 17 and contain additional elements, Applicants submit that these claims are in condition for allowance as well.

Claim 21 recites "where the non-metallic coating material is applied to the surface of the segment of the shaft in a fluid state and cured" and claim 22 recites "coating means..., wherein the coating means is applied in a fluid state and cured." Therefore for similar reasons discussed above with respect to claims 1 and 17, Applicants submit that these claims are allowable over Voyles et al.

Claims 1-5, 7, 8, 12, 13, 15, 17, 18 and 20-23 were rejected under 35 U.S.C. § 102(e) as being anticipated by Nishide et al. (U.S. Pub. No. 2004/0267280A1). Applicants respectfully traverse the rejections.

Nishide et al. disclose a coaxial balloon catheter having radiopaque markers 4 disposed on the inner tube. Nishide et al. say little about the radiopaque markers, but do state: "The material may be of any type, i.e., metal or resin. Moreover, the method of affixing the radiopaque marker 4 is not particularly limited." Paragraph 86. However, Nishide et al. do not teach or suggest that the markers may be created by a "radiopaque coating comprising a

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radiopaque material disposed within a non-metallic coating material that is applied to the surface of the segment...in a fluid state and cured,” as recited in claims 1 and 17. Because the radiopaque marker of Nishide et al. can be anything, it is not inherent that it is a marker having the same structure as that claimed in claims 1 or 17. The disclosure of Nishide et al. thus cannot anticipate the specific structure claimed in claims 1 or 17. A radiopaque marker in Nishide et al. could be, for example, a doped elastic band held in place by tension. Such a marker lacks the structure claimed in claims 1 or 17. Applicants thus submit that claims 1 and 17 are allowable over Nishide et al. As claims 2-5, 7, 8, 12, 13, 15, 18 and 20 depend from either claim 1 or claim 17 and contain additional elements, Applicants submit that these claims are also in condition for allowance.

Claim 21 recites “where the non-metallic coating material is applied to the surface of the segment of the shaft in a fluid state and cured,” claim 22 recites “coating means..., wherein the coating means is applied in a fluid state and cured” and claim 23 recites “the radiopaque portion applied to the surface of the segment of the shaft in a fluid state and cured.” Therefore for the reasons discussed above with respect to claim 1, Applicants submit that these claims are in condition for allowance.

Election/Restriction Requirement

In response to the election/ restriction requirement of November 17, 2004, applicants elected species I, corresponding to claims 1-24. In response to the election/ restriction requirement of February 23, 2005, applicants again elected species I. In this restriction requirement, the examiner placed claim 24 in species II, asserting that it was a process claim. The applicants objected to this characterization, noting that it was a product-by-process claim, and noting that claim 24 should be part of species I and should not be withdrawn. In the office action of April 14, 2005, the examiner agreed that claim 24 was a product-by-process claim, but maintained the withdrawal, asserting that “a product-by process claim is directed to a product that cannot be described structurally. It is clear that applicant’s balloon catheter can be described structurally.” Applicants again objected in the response to this office action, writing “Applicants note that the Examiner considers claim 24 a product-by-process claim. Applicants know of no limitation where product-by-process claims can only be used where the product

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cannot be described structurally. As claim 24 is directed to the species of figure 2, which has been elected, Applicants request that withdrawal of claim 24 by the Examiner be reconsidered."

The office action of September 23, 2005, which this paper is responsive to, fails to respond to this argument. MPEP 707.07(f) states that "[w]here the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it." Applicants therefore request that the Examiner consider this argument.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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